UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

JOANNE MACSWAN Plaintiff, v. MERCK & CO., INC., Defendant.	Case No. 1:20-cv-01661-CCR

DEFENDANT MERCK AND CO., INC.'S MOTION FOR JUDGMENT ON THE PLEADINGS AS TO THE DESIGN DEFECT CLAIMS IN COUNTS I AND II, AND AS TO COUNTS III, IV, V, AND VI OF PLAINTIFF'S COMPLAINT

Pursuant to Federal Rule of Civil Procedure 12(c), Defendant Merck & Co., Inc. ("Merck"), by and through its undersigned counsel, hereby respectfully moves for judgment on the pleadings as to the design defect claims in Counts I and II, and as to Counts III, IV, V, and VI of Plaintiff's Complaint in the entirety. Merck has set forth the grounds upon which this motion is made in the accompanying memorandum of law. A proposed order is attached.

Dated: September 10, 2021.

Respectfully submitted,

/s/ Robert G. Scumaci
Robert G. Scumaci
Gibson, McAskill & Crosby, LLP
69 Delaware Avenue, Suite 900
Buffalo, New York 14202
(716) 856-4200

AND

/s/ Stephen E. Marshall
Stephen E. Marshall
Venable LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
(410) 244-7400

Attorneys for Defendant Merck & Co., Inc.

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MEMORANDUM IN SUPPORT OF DEFENDANT MERCK & CO., INC'S MOTION FOR JUDGMENT ON THE PLEADINGS AS TO THE DESIGN DEFECT CLAIMS IN COUNTS I AND II, AND AS TO COUNTS III, IV, V, AND VI OF PLAINTIFF'S COMPLAINT

Robert G. Scumaci
Gibson, McAskill & Crosby, LLP
69 Delaware Avenue, Suite 900
Buffalo, New York 14202
(716) 856-4200

VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
t. 410-244-7400
f. 410-244-7742

Attorneys for Defendant Merck & Co., Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules and Statutes

Pursuant to Federal Rule of Civil Procedure 12(c), Defendant Merck & Co., Inc. ("Merck"), through its undersigned counsel, respectfully submits this memorandum in support of its motion for judgment on the pleadings as to the design defect claims contained in Counts I and II, and as to Counts III, IV, V, and VI of Plaintiff's Complaint in the entirety.

As set forth in full below, judgment should be entered in Merck's favor as to these claims because Plaintiff's: (1) design defect claims contained in Counts I and II fail to allege the existence of a feasible alternative design as required by New York law and are otherwise preempted by federal law;[1] (2) breach of express warranty claim (Count III) fails to identify the specific statement(s) that allegedly amount to a warranty; (3) breach of implied warranty claim (Count IV) fails to adequately plead the prerequisite elements to support a design defect claim; and (4) fraud claims (Counts V and VI) fail satisfy the particularity dictates of Federal Rule of Civil Procedure 9(b).

I. INTRODUCTION

Plaintiff Joanne MacSwan ("Plaintiff") filed this action in New York Supreme Court on October 6, 2020, alleging that as a result of taking FOSAMAX® ("Fosamax"), Merck's FDA-approved medication for the prevention and treatment of osteoporosis, she suffered "osteonecrosis of the jaw and other irreversible damage to the jaw, [] atrial fibrillation, stroke, and other irreversible damage to the brain." ECF 1-1, Compl. ¶¶ 4, 40-42.[2] Although Plaintiff's Complaint alleges that she began taking Fosamax in January 2009, id. ¶ 40 (a year after generic Fosamax—

[1] Merck recognizes that Counts I and II of Plaintiff's Complaint may also attempt to assert, respectively, claims for negligent failure to warn and strict liability failure to warn, although that is not clear. See ECF 1-1, Compl. ¶¶ 51, 62. Nevertheless, Merck is not moving for judgment on the pleadings with respect to Plaintiff's possible failure to warn claims at this time. If Merck's motion is granted in full, Plaintiff's negligence and strict liability failure to warn claims will thus be the sole remaining causes of action.

[2] Fosamax "falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bones conditions such as osteoporosis and Paget's Disease." ECF 1-1, Compl. ¶ 17.

alendronate—entered the market), it is silent as to when precisely she purportedly sustained these injuries and when (if ever) she ceased taking Merck's branded Fosamax.

Plaintiff's Complaint contains six counts: negligence (Count I); strict liability (Count II); breach of express warranty (Count III); breach of implied warranty (Count IV); fraudulent misrepresentation (Count V); and fraudulent concealment (Count VI).

Count I, entitled "Negligence," is devoid of facts alleging how Merck purportedly was negligent and is vague as to what constitutes Merck's alleged negligence. Nonetheless, Count I arguably attempts to assert a negligent design defect claim (*i.e.*, that Merck "breached this duty by failing to . . . implement any necessary precautions," id. ¶ 51). Count II, entitled "Strict Liability," appears at its core to set forth a strict liability design defect claim (*i.e.*, that Fosamax is "defective in its design and/or formulation, as the foreseeable risks exceeded the benefits associated with its design and/or formulation," id. ¶ 61). Both Counts I and II are devoid of any factual allegations to support a claim that a feasible alternative design was available—a requirement for design defect claims under New York law. Moreover, both Counts make no attempt to overcome the fact that Merck cannot unilaterally alter the design of an FDA-approved medicine like Fosamax, such that Plaintiff's state law design defect claims are preempted by federal law.

Like each of her preceding claims, including her warranty claims (Counts III and IV), Plaintiff's fraud claims (Counts V and VI) are premised on mere formulaic recitations of the elements and are devoid of any factual allegations. Specifically, Plaintiff alleges that Merck: (1) "through its affirmative misrepresentations and omissions, actively concealed from [Plaintiff] and her treating physicians the verified and significant risks associated with taking [Fosamax]," Compl. ¶ 45; (2) "knowingly, and with disregard for the truth and veracity of its statements, made fraudulent representations with respect to [Fosamax] and its associated risks," id. ¶ 89; and (3)

"fraudulently concealed true and accurate information regarding the substantial risks associated with the use of [Fosamax]," id. ¶ 100. Nowhere in her Complaint does Plaintiff identify the specific "affirmative misrepresentations," when they were purportedly made, where they were purportedly made, how they were purportedly made, by whom they were purportedly made, and to whom they purportedly made. Moreover, Plaintiff lodges these conclusory, form allegations of fraud despite simultaneously conceding that as early as 2005 Merck expressly "warn[ed] about the risks associated with osteonecrosis of the jaw"—four years before Plaintiff allegedly began taking Fosamax. Id. ¶ 33. The admission that Merck warned of the relevant risk years before Plaintiff allegedly began taking the medicine flies directly in the face of her claims of fraud, and of course she asserts no facts to support a contention that the FDA-approved warning that Merck provided was inadequate, misleading or could otherwise support a fraud claim.

II. STATEMENT OF FACTS

The FDA first approved Fosamax for use in the United States in 1995. Compl. ¶ 16. In 2008—more than a decade later and with a time-tested proven efficacy and safety record—Merck's patent rights to Fosamax expired.[3] Generic manufacturers then entered the market with alendronate, the generic version of Fosamax, and promptly gained market share.[4]

Throughout the course of its decades-long lifespan, Fosamax has been exhaustively studied by Merck and monitored by the FDA. Compl. ¶ 32. This includes routine safety analyses

[3] See Ex. 1, FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Product Details for ANDA 075710 (ALENDRONATE SODIUM), available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=075710#24587 (last visited Sept. 9, 2021). The Court can take judicial notice of this public fact. E.g., Richardson v. New York City Bd. of Educ., 711 F. App'x 11, 13 (2d Cir. 2017) ("In reviewing a complaint on appeal from a motion to dismiss, we are not precluded 'from taking notice of items in the public record.'") (citation omitted). See also infra note 6.

[4] Cf. Lee Branstetter et al., Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry, 47 Rand J. of Econ. 857, 882 (2016) (explaining that "average branded pharmaceutical product revenues" may erode "by an average of 56%" in the first year following generic entry and that "in later years, branded revenues fall by 89% relative to preentry levels").

conducted by Merck and the FDA regarding Fosamax's purported ability to cause Plaintiff's alleged injuries, specifically osteonecrosis of the jaw ("ONJ") and atrial fibrillation. See id. ¶¶ 31-32. In fact, as Plaintiff concedes, Merck updated its FDA-approved Prescribing Information for Fosamax as early as 2005 to warn expressly about the potential risk of ONJ—four years before Plaintiff's Complaint alleges that she began taking the medicine. Id. ¶ 33. That clear and unambiguous warning, a product of the ongoing safety monitoring by Merck and the FDA, reads:

> **Dental**
>
> Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, and co-morbid disorder (e.g., pre-existing dental disease, anemia, coagulopathy, infection).
>
> Patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy should receive care by an oral surgeon. Dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Ex. 2, 2005 Fosamax Label.[5] Merck also updated its Patient Information Sheet during this period of time to warn that "patients have had jaw problems associated with delayed healing and infection, often following tooth extraction." Ex. 3, 2005 Fosamax PPI. See supra note 5.

[5] When adjudicating a motion to dismiss or for judgment on the pleadings, the Court "may look not only to the complaint but also to documents incorporated into the complaint by reference and relied on by the plaintiffs in bringing suit." Fed. Treasury Enter. Sojuzplodoimport v. SPI Spirits Ltd., 726 F.3d 62, 73 (2d Cir. 2013) (citation omitted). See also Moody v. Allergan USA, Inc., 2017 WL 6949742, at *2 (W.D.N.Y. Dec. 5, 2017) ("Where a plaintiff has relied on the terms and effect of a document in drafting the complaint and that document is thus integral to the complaint, the district court may consider the contents of the document even if it is not formally incorporated by reference.") (citation and internal quotation marks omitted), report and recommendation adopted, 2018 WL 451824 (W.D.N.Y. Jan. 17, 2018).

Moreover, by 2007 the FDA had also already analyzed the alleged association between Fosamax and atrial fibrillation[6] "and did not identify a population of bisphosphonate users at increased risk of atrial fibrillation."[7] The FDA thus did "not believe that healthcare providers or patients should change either their prescribing practices or their use of bisphosphonates at this time." Id. A year later, the FDA updated its ongoing safety review of Fosamax and again concluded that: (1) "across all studies, no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed;" (2) "[i]ncreasing dose or duration of bisphosphonate therapy was also not associated with an increased rate of atrial fibrillation;" and (3) as a result, "healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication."[8]

Despite these well publicized announcements regarding the potential association between Plaintiff's claimed injuries and Fosamax, Plaintiff sued Merck in New York Supreme Court more than a decade later on October 6, 2020, baldly alleging that Merck both fraudulently misrepresented and concealed the very risks that Merck warned of four years before Plaintiff allegedly used Fosamax. ECF 1-1, Compl. ¶¶ 89, 100. Merck removed the case to this Court on

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[6] When adjudicating a motion to dismiss or for judgment on the pleadings, "[a] district court may take judicial notice of public documents issued by government agencies such as the Food and Drug Administration." Moody, 2017 WL 6949742, at *2 (citations omitted). See also In re Zyprexa Prod. Liab. Litig., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) ("Public documents issued by government agencies such as the Food and Drug Administration ('FDA') may also be considered.") (citation omitted); Simon v. Smith & Nephew, Inc., 990 F. Supp.2d 395, 401 n.2 (S.D.N.Y. 2013) (taking judicial notice of public records contained on FDA website).

[7] Ex. 4, FDA, Early Communication of an Ongoing Safety Review on Bisphosphonates: Alendronate (Fosamax, Fosamax Plus D), Etidronate (Didronel), Ibandronate (Boniva), Pamidronate (Aredia), Risedronate (Actonel, Actonel W/Calcium), Tiludronate (Skelid), and Zoledronic acid (Reclast, Zometa) (Oct. 1, 2007), available at https://wayback.archive-it.org/7993/20170722190251/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm070303.htm (last visited Sept. 9, 2021).

[8] Ex. 5, FDA, Update of Safety Review Follow-up to the October 1, 2007 Early Communication about the Ongoing Safety Review of Bisphosphonates (Nov. 12, 2008), available at https://wayback.archive-it.org/7993/20170722190248/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm136201.htm (last visited Sept. 9, 2021).

November 12, 2020. ECF 1. After answering Plaintiff's Complaint and engaging in limited discovery, Merck now moves for judgment on the pleadings with respect to the design defect claims in Counts I and II, and Counts III, IV, V, and VI of Plaintiff's Complaint in their entirety.

III. LEGAL STANDARDS

Rule 12(c) permits a party to move for judgment on the pleadings at any time "[a]fter the pleadings are closed--but early enough not to delay trial." Fed. R. Civ. P. 12(c). "In deciding a Rule 12(c) motion, [the Court] appl[ies] the same standard as that applicable to a motion under Rule 12(b)(6)." Sheppard v. Beerman, 18 F.3d 147, 150 (2d Cir. 1994) (citation omitted). See also Wolf Concept S.A.R.L. v. Eber Bros. Wine & Liquor Corp., 736 F. Supp. 2d 661, 666 (W.D.N.Y. 2010) ("A motion for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure is evaluated under the same standards that apply to a Rule 12(b)(6) motion to dismiss for failure to state a claim.") (citation omitted).

Under that standard, "[t]o survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level." Id. (citations and internal quotation marks omitted). "A formulaic recitation of the elements of [the] cause of action" will not do. See id. at 670. Instead, "a complaint must contain sufficient factual matter, [ ], to state a claim to relief that is plausible on its face." Id. at 666 (citation and internal quotation marks omitted).

Relevant here, a plaintiff's fraud claims must also be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b), "which requires that the plaintiff (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y., 375 F.3d 168, 187 (2d Cir. 2004) (citation and internal quotation marks omitted). See also Apace Commc'ns,

Ltd. v. Burke, 522 F. Supp. 2d 509, 514 (W.D.N.Y. 2007) ("the circumstances constituting fraud or mistake shall be stated with particularity.") (citation and internal quotation marks omitted); Utts v. Bristol–Myers Squibb Co., 226 F. Supp. 3d 166, 189 (S.D.N.Y. 2016) ("fraud, negligent misrepresentation, and fraudulent concealment claims all sound in fraud and are therefore subject to the heightened pleading standards of Rule 9(b)"). The "more demanding" pleading requirements of Rule 9(b) seek to "(1) to provide a defendant with fair notice of the claims against it; (2) to protect a defendant from harm to its reputation or goodwill by unfounded allegations of fraud; and (3) to reduce the number of strike suits." Ferrari Club of Am., Inc. v. Bourdage, 2017 WL 6419061, at *2 (W.D.N.Y. Apr. 25, 2017) (citation and internal quotation marks omitted).

IV. ARGUMENT

A. Plaintiff's negligent and strict liability design defect claims (Counts I and II) should be dismissed because Plaintiff failed to plead the existence of a feasible alternative design and the claim is otherwise preempted by federal law.[9]

1. Plaintiff fails to allege the existence of a feasible alternative design.

Under New York law, a "Plaintiff must [] allege a feasible alternative design to state a claim under a design defect theory." Kennedy v. Covidien, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019). Thus, "[a]lthough a plaintiff need not possess specialized scientific or technical knowledge at the pleading stage, courts have routinely dismissed strict products liability claims premised on a design defect where the plaintiff has failed to plead that it was feasible to design the product in a safer manner." Id. (citation omitted). See also DiBartolo v. Abbott Labs., 914 F.

[9] To the extent Plaintiff claims that her negligence claim (Count I) asserts a design defect claim, that claim should also be dismissed for the same reasons set forth herein: Plaintiff failed to plead the existence of a feasible alternative design, and the claim is otherwise preempted by federal law. See S.F. v. Archer Daniels Midland Co., 594 F. App'x 11, 12 (2d Cir. 2014) ("S.F.'s claims for negligence, gross negligence, and strict products liability based in design defects fail because she did not allege a safer alternative design for high fructose corn syrup . . . . New York courts generally consider strict products liability and negligence claims to be functionally synonymous.") (citations and internal quotation marks omitted).

Supp. 2d 601, 623 (S.D.N.Y. 2012) (dismissing strict liability and negligent design defect claims because "plaintiff fails to allege that . . . Abbott feasibly could have designed Humira more safely"); Reed v. Pfizer, Inc., 839 F.Supp.2d 571, 578 (E.D.N.Y. 2012) (dismissing design defect claim under New York law because "Plaintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer"); Oden v. Bos. Sci. Corp., 330 F. Supp. 3d 877, 889 (E.D.N.Y. 2018) ("Plaintiff's design defect claim also fails on the independent ground that the Complaint does not plead the existence of a feasible alternative design."), adhered to on reconsideration, 2019 WL 1118052 (E.D.N.Y. Mar. 11, 2019).

Here, Plaintiff fails to allege anywhere in her Complaint how Fosamax could have been designed in a safer manner. She offers no change to the chemical compound that ostensibly would have made the medicine safer. Instead, she merely points to the purported availability of "several" unidentified "alternative safer products" that she could have used. See Compl. ¶ 36 ("Consumers, including Ms. MacSwan, who used [Fosamax] . . . had several alternative safer products available to treat their conditions."). See also Compl. ¶ 61 ("Further, [Fosamax] posed a greater risk than other similar medications").[10]

Under New York law, however, "[a] plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used." Hilaire v. DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014). See also Simon, 990 F.Supp.2d at 405 ("an allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of design defect");

[10] Plaintiff's claims of "alternative safer products" are also belied by her own allegations that the risks of ONJ and atrial fibrillation extended beyond Fosamax to all other drugs within same "class of bisphosphonates." See, e.g., Compl. ¶ 18 ("medical articles and studies appeared reporting the frequent and common occurrence of [ONJ] as a result of nitrogenous bisphosphonates"); id. ¶ 19 ("medical articles and studies appeared reporting the frequent and common occurrence of atrial fibrillation as a result of bisphosphonates use"); id. ¶ 20 ("Defendant knew, or should have known, that [Fosamax], as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates").

Goldin v. Smith & Nephew, Inc., 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013) ("the question is whether a safer alternative design for *this* product existed—and, more precisely, whether Plaintiff has alleged that fact in her Complaint"); Pinello v. Andreas Stihl AG & Co. KG, 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011) (holding that plaintiff's reliance on an "entirely different product" did not constitute evidence of a feasible alternative design). Accordingly, Plaintiff's design defect claims in Counts I and II should be dismissed.

2. Plaintiff's design defect claims are preempted by federal law.

Even if this Court holds that Plaintiff is not obligated to plead the existence of a feasible alternative design, Plaintiff's state law design defect claims concerning a medicine that the FDA has deemed safe and effective up through the present should be dismissed because it is preempted by federal law. See, e.g., Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 300 (6th Cir. 2015) (holding under New York law that plaintiff's "post-approval design defect claims are preempted by federal law"); Utts, 226 F. Supp. 3d at 182 (stating that "a post-approval design defect claim is clearly preempted by federal law where FDA regulations prohibit a change of the type implicated by the claim") (citations and internal quotation marks omitted).

"The Supremacy Clause provides that the laws and treaties of the United States 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 479-80 (2013) (citation omitted). It has therefore "long been settled that state laws that conflict with federal law are 'without effect.'" Id. at 479-80 (citations omitted). Moreover, "[e]ven in the absence of an express pre-emption provision, the [Supreme] Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements'"—*i.e.*, impossibility preemption. Id. (citations omitted). The question of whether a state law is preempted

"is a legal one for the judge, not a jury." Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679-80 (2019) ("The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute. Moreover, judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination.").

Fosamax, and its generic equivalent alendronate, are regulated by the FDA and subject to the dictates of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDCA requires manufacturers of medicines like Fosamax to gain FDA approval by demonstrating that the medicine is safe and effective when used in accordance with the Prescribing Information before marketing any drug in interstate commerce. 21 U.S.C. § 355(a). And "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Bartlett, 570 U.S. at 477 (citation omitted).

Importantly, within the realm of FDA-approved products, the Supreme Court has held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." PLIVA, Inc. v. Mensing, 564 U.S. 604, 623-24 (2011) (holding that failure to warn claim against generic drug manufacturer was preempted because manufacturer could not have changed the drug label without FDA approval). In Bartlett, the Court thus held that the plaintiff's design defect claim was preempted because the manufacturer could not "redesign" the FDA-approved drug to comply with a state law duty to "reduc[e] its 'risk of danger'" without first obtaining FDA approval. See 570 U.S. at 483-84 ("Indeed, were Mutual to change the composition of its [product], the altered

chemical would be a new drug that would require its own [New Drug Application] to be marketed in interstate commerce.") (citation omitted).

Since Bartlett, courts have routinely dismissed as preempted design defects claims involving FDA-approved products when the defendant cannot change the design unilaterally. See, e.g., In re Fosamax Prods. Liab. Litig., 965 F. Supp. 2d 413, 420 (S.D.N.Y. 2013) ("*Bartlett* squarely preempts design defect claims . . . based upon chemical composition flaws"); Yates, 808 F.3d at 300 (holding under New York law that plaintiff's "post-approval design defect claims are preempted by federal law"); Utts, 226 F. Supp. 3d at 182 (stating that "a post-approval design defect claim is clearly preempted by federal law where FDA regulations prohibit a change of the type implicated by the claim") (citations and internal quotation marks omitted); In re Zantac (Ranitidine) Prods. Liab. Litig., 512 F. Supp. 3d 1278, 1292 (S.D. Fla. 2021) ("A claim that a brand-name drug manufacturer should have changed a drug's FDA-approved formulation is a pre-empted claim because the manufacturer cannot make such a change independently and while remaining in compliance with federal law.") (citations omitted).

The court should follow suit here. Plaintiff's design defect claim expressly alleges that Fosamax was "defective in its design and/or formulation, as the foreseeable risks exceeded the benefits associated with its design and/or formulation." Compl. ¶ 61. But because the FDA approved Fosamax and generic alendronate for sale in the United States, and continues to approve it as designed, Merck is prohibited "from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients.'" Bartlett, 570 U.S. at 477 (citation omitted). Thus, because federal law precludes Merck from unilaterally making the changes implicated by Plaintiff's claim—*i.e.*, implementing the as yet undisclosed alternative

design—Plaintiff's design defect claim is preempted by federal law and should be dismissed with prejudice.

B. Plaintiff's breach of express warranty claim (Count III) should be dismissed because Plaintiff failed to identify the specific statement(s) that amount to a warranty.

Breach of express warranty claims under New York law require "(i) a *material statement* amounting to a warranty; (ii) the buyer's *reliance* on this warranty as a basis for the contract with his immediate seller; (iii) the *breach* of this warranty; and (iv) injury to the buyer *caused* by the breach." Avola v. La.-Pac. Corp., 991 F. Supp. 2d 381, 391 (E.D.N.Y. 2013) (emphasis in original) (citations omitted). "As is clear from the standard, the actual 'material statement amounting to a warranty' is critically important; it is so critical that courts require parties to specifically identify the statement even at the motion-to-dismiss stage." Hume v. Lines, 2016 WL 1031320, at *5 (W.D.N.Y. Mar. 8, 2016) ("to state a claim for breach of express warranty, the injured party must identify in the complaint the 'specific words, promises or statements' made by the defendant") (citation omitted). Moreover, "[t]he injured party must provide detail about '*where, when* or *how* the alleged promise or statement was provided.' A failure to be specific about the express warranty at issue is fatal to the claim." Id. (citations omitted).

Given these requirements, it is well established that courts dismiss breach of express warranty claims when the "plaintiff fails to state what was expressly warranted by defendant." Richman v. W.L. Gore & Assocs., Inc., 881 F. Supp. 895, 905 (S.D.N.Y. 1995), modified on other grounds, 988 F. Supp. 753 (S.D.N.Y. 1997). See also Gelber v. Stryker Corp., 752 F. Supp. 2d 328, 335 (S.D.N.Y. 2010) ("Plaintiffs have failed to allege any affirmative statement made by Defendants regarding the safety or effectiveness of the product on which Plaintiffs actually relied . . . . Therefore, the Court finds that [they fail] to meet the *Twombly* pleading standard"); Teixeria v. St.

Jude Med. S.C., Inc., 193 F. Supp. 3d 218, 225 (W.D.N.Y. 2016) ("These bare-bones allegations are too generic to set forth a claim for breach of an express warranty") (citation omitted).

Simply put, Plaintiff's Complaint fails to identify the specific terms of any alleged express warranty. To the contrary, Plaintiff generically alleges that "[u]pon information and belief, through its advertising and otherwise, [Merck] expressly represented to [Plaintiff] that [Fosamax] had been adequately tested, was to be prescribed in accordance with its intended uses, was of merchantable quality, and was not dangerous." Compl. ¶ 70. Such boilerplate allegations neither "identify . . . the 'specific words, promises or statements'" allegedly made by Merck nor "provide detail about '*where, when* or *how* the alleged promise or statement was provided.'" Hume, 2016 WL 1031320, at *5 (emphasis in original).

Furthermore, Plaintiff's decision to plead her express warranty claim based "[u]pon information and belief" must fail because that practice is permissible only "where the facts are peculiarly within the possession and control of the defendant or where the belief is based on factual information that makes the inference of culpability plausible." Teixeria, 193 F. Supp. 3d at 225–26 (citations and internal quotation marks omitted). Of course, in the context of breach of express warranty claims, "whether representations were made to Plaintiff or [her] medical providers are factual matters that are peculiarly within the possession of *Plaintiff [herself]* or could be obtained by Plaintiff simply asking [her] doctors or reviewing [her] own medical records." Id. at 226 (emphasis in original). Thus, "[f]or Plaintiff to make an allegation 'on information and belief' in such circumstances is an improper use of this pleading device," and such a "speculative allegation does not assist Plaintiff in stating a claim for breach of express warranty." Id. Count III of Plaintiff's Complaint should be dismissed.

C. Plaintiff's breach of implied warranty claim (Count IV) should be dismissed because Plaintiff failed to plead the prerequisite elements to support a design defect or manufacturing defect claim.

Under New York law, a plaintiff must allege the following elements to adequately plead a claim based upon breach of an implied warranty: "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect was the proximate cause of the injury." Oden v. Bos. Sci. Corp., 330 F. Supp. 3d at 895 (citations omitted). Because "a breach of implied warranty claim requires that [a] Plaintiff plead sufficient factual allegations that the [product] was defectively designed or manufactured," the breach of implied warranty claim "fails as a matter of law" if Plaintiff has also failed to plead the necessary elements to support a design defect or manufacturing defect claim. Id. at 895-96 (citation omitted). See also Morrison v. Hoffmann-La Roche, Inc., 2016 WL 5678546, at *11 (E.D.N.Y. Sept. 29, 2016) ("Plaintiff's defective design claim fails and, thus, the breach of implied warranty claim fails as well.") (citation omitted); Simon, 990 F. Supp. 2d at 407 ("the Amended Complaint fails to allege that a non-PMA approved device was defectively designed. It thus fails to state a claim for breach of implied warranty.") (citation omitted). In short, because Plaintiff's design defect claim should be dismissed, see Section IV.A. supra, Merck is also entitled to judgment in its favor on Plaintiff's breach of implied warranty claim.[11]

[11] In the event that this Court holds that Plaintiff is not required to plead a feasible alternative design but that her design defect claim is nonetheless preempted, Plaintiff's breach of implied warranty claim would also be preempted. E.g., Drager v. PLIVA USA, Inc., 741 F.3d 470, 479 (4th Cir. 2014) ("to the extent that implied warranties of merchantability or fitness for a particular purpose can arise in this context [*i.e.*, prescription drugs] under Maryland law, they are preempted by the requirements of the FDCA"); In re Pamidronate Prods. Liab. Litig., 842 F. Supp. 2d 479, 485 (E.D.N.Y. 2012) (holding that "Plaintiffs' breach of implied warranty claim necessarily alleges that defendants should have changed the design of pamidronate to make it 'safe and fit for its intended uses'" and is therefore preempted because "defendants were prohibited by federal law from changing the design of pamidronate") (citation omitted).

D. Plaintiff's fraud claims (Count V and Count VI) should be dismissed for failure to satisfy the particularity requirements of Rule 9(b).

Under New York law, "[t]he elements of viable claims of affirmative fraud, fraudulent concealment and negligent misrepresentation are similar. To demonstrate a prima facie claim of fraud, a plaintiff must demonstrate by clear and convincing evidence the existence of a representation of material fact, falsity, scienter, justifiable reliance and injury." Rose v. Am. Tobacco Co., 787 N.Y.S.2d 681 (Sup. Ct. 2004), on reargument sub nom. Rose v. The Am. Tobacco Co. (N.Y. Sup. Ct. Sept. 27, 2004). See also Utts v. Bristol–Myers Squibb Co., 226 F. Supp. 3d at 189 ("fraud, negligent misrepresentation, and fraudulent concealment claims all sound in fraud and are therefore subject to the heightened pleading standards of Rule 9(b)").

When considering a motion for judgment on the pleadings, Rule 9(b) thus requires that Plaintiff "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Eternity Glob. Master Fund Ltd., 75 F.3d at 187 (citation and internal quotation marks omitted). See also United States ex rel. Polansky v. Pfizer, Inc., 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) ("Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.").

In this case, Plaintiff has entirely failed to provide the who, what, when, where and how of the alleged fraud—especially considering Plaintiff's concession that four years before she purportedly used Fosamax, Merck added, and the FDA approved, a warning about ONJ, the very risk at issue. Lacking critical case-specific facts, Plaintiff instead simply lodged the following boilerplate allegations:

- "[Merck] concealed its knowledge of [Fosamax's] unreasonably dangerous risks from [Plaintiff], other consumers, and the medical community." Compl ¶ 2.

- "[Merck], through its affirmative misrepresentations and omissions, actively concealed from [Plaintiff] and her treating physicians the verified and significant risks associated with taking [Fosamax]." Compl. ¶ 45.

- "[Merck] knowingly, and with disregard for the truth and veracity of its statements, made fraudulent representations with respect to [Fosamax] and its associated risks." Id. ¶ 89.

- "[Merck] fraudulently concealed true and accurate information regarding the substantial risks associated with the use of [Fosamax]." Id. ¶ 100.

Plaintiff, however, fails to square any of those bald allegations with the fact that Merck provided a warning about the specific risk at issue in this case.

Entirely absent from Plaintiff's Complaint is her identification of (1) the specific "verified and significant risks" Merck purportedly concealed from her or her physicians despite the FDA-approved warning; (2) the "true and accurate information regarding the substantial risks" that Merck purportedly concealed from her or her physicians that was not included in the warning; (3) the specific affirmative misrepresentations that Merck purportedly made to her or her physicians; (4) who purportedly made those affirmative misrepresentations to her or her physicians; (5) how Merck purportedly made those affirmative misrepresentations; and (6) when Merck purportedly made those affirmative misrepresentations. This, including the identities of her physicians, is all information that (assuming her claims are viable) should be available to Plaintiff and should have been included in her Complaint.

Where, as here, a Plaintiff's allegations wholly fail to provide the requisite level of precision required by Rule 9(b), this Court has not hesitated to dismiss fraud claims. See Ferrari Club of Am., Inc., 2017 WL 6419061, at *3 (dismissing fraud claims because the allegations "woefully miss[] the 9(b) particularity mark: no statements are specified, no speaker is identified, no time or place of the statements is identified, and no explanation as to why said statements are fraudulent appears in the amended complaint"); Amos v. Biogen Idec Inc., 28 F. Supp. 3d 164, 172–73

(W.D.N.Y. 2014). Indeed, in Amos, this Court explained that simply reciting "general allegations of fraudulent conduct" is insufficient to avoid dismissal:

> . . . . plaintiff's allegations of fraud have not been alleged with sufficient particularity. For example, although plaintiff alleges that the defendants paid ghostwriters to author articles favorable to the use of Tysabri, no such article is identified. Similarly, although the plaintiff alleges that the defendants knew of and suppressed information regarding 12 suspected cases of PML linked to Tysabri, that allegation is made only on information and belief, and no further details are alleged. Plaintiff further claims that defendants made misrepresentations in advertisements, website statements, written and oral information provided to patients and doctors and other marketing materials, but fails to identify any such misrepresentation, and fails to explain why such misrepresentations were fraudulent. These general averments of fraud lack the particularity required by Rule 9(b), and therefore, I grant defendants' motion to dismiss plaintiff's fraud claims.

Id.

Here, Plaintiff's threadbare allegations are even more deficient than those that failed in Amos. In Amos, the plaintiff at least provided allegations of ghostwriting and generally claimed that misrepresentations were made in "advertisements, website statements, written and oral information provided to patients and doctors and other marketing materials." Id. Plaintiff in this case, however, has failed to even identify the specific vehicle(s) through which Merck apparently made misrepresentations—much less the content of those purported misrepresentations, the date(s) on which they were made, and by whom they were made. See Loewy v. Stuart Drug & Surgical Supply, Inc., 1999 WL 76939, at *5 (S.D.N.Y. Feb. 11, 1999) (dismissing Plaintiff's fraud claim for failure to "extract quotes from the relevant materials, provide copies of the offending documents, state where and when any misleading materials were distributed, refer to particular individuals who made misleading statements to doctors and patients, or detail when and where those misleading statements may have been made" in the complaint.), adhered to on reconsideration, 1999 WL 216656 (S.D.N.Y. Apr. 14, 1999). Consequently, Plaintiff's generic,

formulaic fraud claims should be dismissed for failure to satisfy the particularity requirements of Rule 9(b).

V. CONCLUSION

For each of the reasons set forth above, Merck's motion for judgment on the pleadings should be granted with prejudice as to the design defect claims in Counts I and II and as to Counts III, IV, V and VI of Plaintiff's Complaint in the entirety.

Dated: September 10, 2021

Respectfully submitted,

/s/ Robert G. Scumaci
Robert G. Scumaci
Gibson, McAskill & Crosby, LLP
69 Delaware Avenue, Suite 900
Buffalo, New York 14202
(716) 856-4200

AND

/s/ Stephen E. Marshall
Stephen E. Marshall
Venable LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
(410) 244-7400

Attorneys for Defendant Merck & Co., Inc

CERTIFICATE OF SERVICE AND COURTESY COPY TO CHAMBERS

The undersigned hereby certifies that, on September 10, 2021, Merck's motion for judgment on the pleadings as to the design defect claims in Counts I and II, and as to Counts III, IV, V, and VI of Plaintiff's Complaint in the entirety, memorandum in support of Merck's motion for judgment on the pleadings, and proposed order were filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/s/ Robert G. Scumaci
Robert G. Scumaci
Gibson, McAskill & Crosby, LLP
69 Delaware Avenue, Suite 900
Buffalo, New York 14202
(716) 856-4200

Attorneys for Defendant Merck & Co., Inc.